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HOUSE BILL NO. 1995**AMENDMENT IN THE NATURE OF A SUBSTITUTE**(Proposed by the House Committee on Appropriations
on January 25, 2021)

(Patron Prior to Substitute—Delegate Murphy)

A BILL to amend the Code of Virginia by adding in Chapter 2 of Title 32.1 an article numbered 19, consisting of sections numbered 32.1-73.14 through 32.1-73.17, relating to Rare Disease Council; Rare Disease Council Fund; report.

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Chapter 2 of Title 32.1 an article numbered 19, consisting of sections numbered 32.1-73.14 through 32.1-73.17, as follows:

*Article 19.**Rare Disease Council.***§ 32.1-73.14. Rare Disease Council; purpose.**

There is hereby created in the executive branch of state government the Rare Disease Council (the Council) for the purpose of (i) advising the Governor and the General Assembly on the needs of individuals with rare diseases in the Commonwealth; (ii) identifying challenges that such individuals face, including delays in obtaining a diagnosis or the receipt of a misdiagnosis, shortages of medical specialists who can provide treatment, and lack of access to therapies and medication used to treat rare diseases; (iii) funding research related to rare diseases and the development of new treatments for rare diseases; and (iv) funding for supports for persons with rare diseases in the Commonwealth.

§ 32.1-73.15. Powers and duties of the Council.

The Council shall have the power and duty to:

1. Within the first year, hold public hearings and make inquiries of and solicit comments from the public to assist the Council in understanding the scope of rare diseases in the Commonwealth and the impact of rare diseases on individuals in the Commonwealth.

2. Conduct research and consult with experts to develop policy recommendations related to:

a. Improving access to health care and other services for individuals with rare diseases, including access to health insurance, specialists, health care services, and other necessary services for individuals with rare diseases;

b. The impact of health insurance coverage, cost sharing, tiers, or other utilization management procedures on access to health care and other necessary services; and

c. The impact of providing coverage under the state program for medical assistance services for approved health care services and medications for rare diseases.

3. Publish a list of existing publicly accessible resources on research, diagnosis, treatment, and education relating to rare diseases on the Council's webpage.

4. Submit annually by October 1 a report to the Governor and the General Assembly for publication as a report document as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents and reports. The annual report shall (i) describe the activities and recommendations of the Council and (ii) describe the status of funding available to the Council, including information regarding any grants applied for and received by the Council.

5. Apply for, accept, and expend gifts, grants, and donations from public or private sources to enable the Council to better carry out its objectives.

§ 32.1-73.16. Membership; terms; quorum; meetings; staffing.

A. The Council shall have a total membership of 21 members that shall consist of 18 nonlegislative citizen members and three ex officio members. The Governor shall appoint a chairman and vice-chairman who shall be residents of the Commonwealth and shall not be employed by any federal or state government. Nonlegislative citizen members shall be appointed by the Governor and shall include, in addition to the chairman and the vice-chairman, one representative from an academic research institution in the Commonwealth that receives any grant funding for rare disease research; one geneticist licensed and currently practicing in the Commonwealth; one registered nurse or advanced practice registered nurse licensed and currently practicing in the Commonwealth, with experience in treating rare diseases; two physicians with expertise in rare diseases who are licensed and currently practicing medicine in the Commonwealth; one hospital administrator, or his designee, from a hospital in the Commonwealth that provides care to persons diagnosed with rare diseases; two persons who are 18 years of age or older who have been diagnosed with a rare disease; two caregivers of persons with a rare disease; two representatives of rare disease patient organizations operating in the Commonwealth; one licensed pharmacist with experience with drugs used to treat rare diseases; one representative from the biopharmaceutical industry; one representative from health plan companies; and

60 one member from the scientific community who is engaged in rare disease research, which may include
61 a medical researcher with experience conducting research on rare diseases. The Commissioner of
62 Health, the Director of the Department of Medical Assistance Services, and the Superintendent of Public
63 Instruction, or their designees, shall serve ex officio with nonvoting privileges. Ex officio members of the
64 Council shall serve terms coincident with their terms of office.

65 Nonlegislative citizen members of the Council shall be citizens of the Commonwealth. Appointments
66 to fill vacancies, other than by expiration of a term, shall be for the unexpired terms. Vacancies shall be
67 filled in the same manner as the original appointments. After the initial staggering of terms,
68 nonlegislative citizen members shall be appointed for a term of three years.

69 Ex officio members of the Council shall serve terms coincident with their terms of office.
70 Appointments to fill vacancies, other than by expiration of a term, shall be for the unexpired terms.
71 Vacancies shall be filled in the same manner as the original appointments. After the initial staggering of
72 terms, nonlegislative citizen members shall be appointed for a term of four years.

73 B. The Council shall meet quarterly and the chairman and vice-chairman shall establish a meeting
74 schedule on an annual basis. A majority of the members shall constitute a quorum.

75 C. Members of the Council shall serve without compensation or reimbursement.

76 D. The Department of Health shall provide staff support to the Council. All agencies of the
77 Commonwealth shall provide assistance to the Council, upon request.

78 **§ 32.1-73.17. Rare Disease Council Fund.**

79 There is hereby created in the state treasury a special nonreverting fund to be known as the Rare
80 Disease Council Fund, referred to in this section as "the Fund." The Fund shall be established on the
81 books of the Comptroller. All funds appropriated for such purpose and any gifts, grants, donations, and
82 other funds received on its behalf shall be paid into the state treasury and credited to the Fund. Interest
83 earned on moneys in the Fund shall remain in the Fund and be credited to it. Any moneys remaining in
84 the Fund, including interest thereon, at the end of each fiscal year shall not revert to the general fund
85 but shall remain in the Fund. Moneys in the Fund shall be used solely for the purpose of (i) funding
86 research related to rare diseases and the development of new treatments for rare diseases and supports
87 for persons with rare diseases in the Commonwealth and (ii) supporting the work of the Council.
88 Expenditures and disbursements from the Fund shall be made by the State Treasurer on warrants issued
89 by the Comptroller upon written request signed by the Commissioner of Health.

90 **2. That the first meeting of the Rare Disease Council shall occur within 90 days of its effective**
91 **date, July 1, 2021.**

92 **3. That the initial appointments of nonlegislative citizen members of the Rare Disease Council shall**
93 **be staggered as follows: (i) two persons who are 18 or older who have been diagnosed with a rare**
94 **disease, two caregivers of persons with a rare disease, and two representatives of rare disease**
95 **patient organizations operating in the Commonwealth shall be appointed for a term of one year;**
96 **(ii) one licensed pharmacist, one registered nurse or advanced practice registered nurse licensed**
97 **and currently practicing medicine in the Commonwealth, and the chairman and vice-chairman**
98 **appointed by the Governor shall be appointed for a term of two years; (iii) one hospital**
99 **administrator, or his designee, one representative from the biopharmaceutical industry, and one**
100 **representative from health plan companies shall be appointed for a term of three years; and (iv)**
101 **one representative from an academic research institution in the Commonwealth that receives any**
102 **grant funding for rare disease research, one geneticist licensed and currently practicing in the**
103 **Commonwealth, two physicians with expertise in rare diseases who are licensed and currently**
104 **practicing medicine in the Commonwealth, and one member from the scientific community who is**
105 **engaged in rare disease research shall be appointed for a term of four years.**